DEC - 4 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The Assigned 510(k) Number is: K092620

1. Submitter Information

- **Manufacturer Name and Address:**
  Beijing Choice Electronic Technology Co., Ltd.
  Bailangyuan Building B, Rm. 1127-1128, Fuxing Road, A36
  Beijing, China 100039

  Beijing Choice Electronic Technology Co., Ltd.
  No.9 Shuangyuan Rd., Badachu Hi-tech Zone, Shijingshan District
  Beijing, China 100041

- **Contact Person:**
  Ms. Yajing Li
  North Building 3F, No. 9 Shuangyuan Rd.,
  Badachu Hi-tech Zone, Shijingshan District Beijing China 100041
  Phone: +86-10-88790480 Ext.6046
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  Email: liyajing@choicemmed.com & cc@choicemmed.com

- **Date prepared:**
  March 12, 2009

2. Applicant Device Information

- **Trade/Proprietary Name:** MD300C318 Fingertip Pulse Oximeter
- **Common Name:** Pulse Oximeter
- **Classification:** 21CFR 870.2700 Oximeter Class: II

3. Legally Marketed Predicate Device

Finger Pulse Oximeter model 9560
K-number: K081285
NONIN MEDICAL, INC.

4. Device Description

The applicant device MD300C318 is a Finger Pulse Oximeter, which designed with the measurement, storage, review, audible alarms, visible alarms, vibration alert for finger-out, low battery voltage alarm function, and data transmission (optional) functions. The power source of the applicant device is 2*AAA Typical lithium ion batteries.

The Pulse Oximeter consists of detector and emitter LED, signal amplify unit, CPU, data display unit and power unit, and with Bluetooth® communication which is integrated into a telemedicine system or other health data collection system through the wireless connection.

The Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 940 nm, which is ultra red light. Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

The applicant device is not for life-supporting or life-sustaining, not for implant. The device or transducers are not sterile and the transducer is reusable and does not need sterilization or re-sterilization. The device is for prescription. The device does not contain drug or biological products.

5. Intended use

The MD300C318 Fingertip Pulse Oximeter is intended for continuous use or spot checking in measuring and displaying functional arterial oxygen saturation (SpO2) and pulse rate of patients in hospitals and home care. It is intended for adult and pediatric patients on finger between 0.3-1.0 inch (0.8 - 2.5 cm) thick.

6. Effectiveness and Safety Considerations

The applicant device is compliance with IEC60601-1, Medical electrical equipment - Part 1: General requirements for safety and IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility -.

Requirements and tests.
The Software Validation is in compliance with FDA Guidance to Compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices".
The Clinical Test reports following ISO 9919:2005, Medical electrical equipment - Particular requirements for the safety and essential performance of pulse oximeter.
The applicant device has successfully undergone both bench and human testing to support the determination of substantial equivalence.

7. Substantially Equivalence Determination

The applicant device MD300C318 Fingertip Pulse Oximeter has same classification information, same intended use, same design principle, same specifications, same product materials and performance effectiveness as the predicate device. These are no obvious differences to influence the effectiveness and safety of the device.

8. Conclusion

The applicant device MD300C318 Fingertip Pulse Oximeter is Substantially Equivalent (SE) to the predicate device which is US legally market device. Performance test results do not raise new questions of safety and effectiveness when compared to the legally marketed devices. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Yajing Li
Beijing Choice Electronic Technology Company, Limited
North Building 3F, No. 9 Shuangyuan Road,
Badachu Hi-tech Zone, Shijingshan District
Beijing
CHINA 100041

DEC - 4 2009

Re: K092620
Trade/Device Name: MD300C318 Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 1, 2009
Received: December 1, 2009

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092620

Device Name: MD300C318 Fingertip Pulse Oximeter

Indications for Use:

The MD300C318 Fingertip Pulse Oximeter is intended for continuous use or spot checking in measuring and displaying functional arterial oxygen saturation (SpO2) and pulse rate of patients in hospitals and home care. It is intended for adult and pediatric patients on finger between 0.3-1.0 inch (0.8 - 2.5 cm) thick.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schutt

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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